

AMENDMENTS TO THE SPECIFICATION

Please replace the Abstract with the following:

--The present invention provides a device and method for occluding the body lumen including the cystic duct, wherein, in one embodiment, the device has a plurality of openings. In use, using a suitable access instrument, the device is inserted into the cystic duct, and a biological bonding agent, such as that comprising biphasic, biosorbable, or shape memory material, is extruded through the openings to lodge the device in the duct and to occlude the duct. The access instrument may then be detached from the device and withdrawn. The device is left in the duct, acting as a plug.--

In section [0001], please amend as follows:

This invention relates to medical devices, methods for making them, and methods for their use. More particularly, the present invention relates to the methods and devices for occluding body lumens by delivering a plugging means into a lumen with or through a detachable access catheter. In one exemplary use, ~~The~~ the invention may be used to occlude the cystic duct for preventing bile leakage in the field of treating gallstone and gallbladder disease.

In section [0005], please amend as follows:

Gallstones usually produce noticeable symptoms by causing inflammation, narrowing (stenosis) or obstruction of the cystic duct, common bile duct or sphincter following their exit from the gallbladder. Although there has been some success with drug- or shockwave-mediated dissolution of gallstones, the current therapy of choice is surgery, either by excision of the gallbladder (cholecystectomy) or draining the gallbladder with a tube (cholecystostomy).

Harrison's Principles of Internal Medicine, Twelfth Edition, McGraw-Hill, Inc., New York, N.Y., pp. 1358-1368 (1991). In 1991 approximately 600,000 patients underwent cholecystectomy. Gallstones and Laparoscopic Cholecystectomy, NIH Consens Statement Online 1992 Sep 14-16;10(3):1-20. 25 June 2001 <http://odp.od.nih.gov/consensus/cons/090/090_statement.htm>.

In section [0010], please amend as follows:

Although the management of acute acalculous cholecystitis following heart surgery remains controversial, percutaneous transhepatic gallbladder drainage is found to be a safe and effective procedure. Ishikawa, S., Ohtaki, A., Koyano T., Takahashi T., Sato, Y., Nakamura, S., Ohwada, S., Morishita, Y. ; "Percutaneous transhepatic gallbladder drainage for acute acalculous cholecystitis following cardiovascular surgery." *J. Cardiovasc. Surg.* 38.5 (1997): 513-5. The drainage (cholecystostomy) is for temporary management (to get over infection), and at the present time, cystic duct occlusion is permanent and should be part of gallbladder removal or, in this case, defunctionalization. In such cases, catheter-guided occlusion of the cystic duct would be ~~an~~ a useful, adjunctive therapy in conjunction with chemical or mechanical ablation of the mucosa to defunctionalize the gallbladder.

In section [0013], please amend as follows:

In one embodiment, the means for plugging comprises a tapered segment, and the means for fixing comprises an expandable segment which is generally adjacent to the tapered segment.

In another embodiment, the expandable segment further includes structures suitable for attaching the expandable segment to the interior wall of the lumen. In some embodiments, the structures for attaching the means for plugging to the interior wall of the lumen have a shape like tooth tooth-like shape, or hook, or the like. In other embodiments, the means for fixing comprises a segment having numerous openings of suitable sizes, shapes, and spaces between them.

In section [0015], please amend as follows:

In one embodiment of the method of the present invention, using a suitable delivery instrument, the means for plugging is inserted into a target lumen, moved to a selected location, and then fixed to the interior wall of the lumen. The delivery instrument is then detached from the means for plugging and withdrawn from the lumen, leaving the means for plugging in the selected location as an occluding device. While at the present time, and as it concerns occlusion of the cystic duct, the present assertion may be used to permanently plug or occlude a body lumen, the present invention is intended to encompass semi-permanent or temporary plugging or occlusion of body lumens.

In section [0037], please amend as follows:

Fig. 4 shows another embodiment of the occlusion device 100 in which the plugging means 22 further comprises a plurality of openings 102. These openings 102 may be evenly or unevenly spaced from each other, and their shapes may be round, oval or any other shape suitable for allowing the passage or flow-through of a biological bonding agent. To occlude the cystic duct 14 or other body lumen, the operator will inject a biological bonding agent such as a surgical glue or tissue bonding or binding agent into the access catheter 26. After sliding down to the plugging means 22, the surgical glue or tissue bonding or binding agent will extend or extrude through the openings 102, and bind the plugging means 22 to the interior wall 18 of the cystic duct 14. The operator may then detach and withdraw the access catheter 26.

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